**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF OHIO**
**WESTERN DIVISION**

MYRTLE THOMPSON,

Plaintiff,

v.

DEPUY ORTHOPAEDICS, INC., et al.,

Defendants.

CASE NO.: 1:13-CV-00602

Judge Michael R. Barrett

**OPINION AND ORDER**

This matter is before the Court on Defendant DePuy Orthopaedics, Inc.'s Motion for Summary Judgment (Doc. 29). Plaintiff Myrtle Thompson has filed a response in opposition (Doc. 41), and Defendant DePuy Orthopaedics, Inc. has filed a reply (Doc. 45).

## I. FACTUAL BACKGROUND

The following is a summary of the facts, construed in the light most favorable to Thompson.

### A. Bone Cement Generally

Bone cement consists of a liquid and powder component, which are packaged separately and mixed together at the direction of the orthopedic surgeon at the appropriate stage of joint replacement surgery. (Doc. 34, PageId 1108-11; Doc. 35, PageId 1296). The powder component consists mainly of polymer poly (methyl methacrylate) ("PMMA") and includes a radiopacificer to make the cement visible on x-rays. (Doc. 34, PageId 1109; Doc. 35, PageId 1296). The liquid component is a methyl methacrylate ("MMA") monomer which is added to the powder to create a heat-generating (exothermic) reaction. (Doc. 34, PageId 1108; Doc. 35, PageId 1296). The result is a doughy mixture that is applied by the surgeon. (Doc. 35, PageId

1296). Bone cement has no inherent adhesive properties; it functions more as a grout between the bone and the implant. (Doc. 33, PageId 984; Doc. 34, PageId 1115-16; Doc. 35, PageId 1296-97).

DePuy purchases the PMMA powder component from MV Plastics, Ltd. (Doc. 35, PageId 1297). The powder contains PMMA particles with a median size of 39 microns. (Doc. 35, PageId 1297). For the bone cements that contain the antibiotic Gentamicin, DePuy has purchased the Gentamicin powder from Lek d.d. Solvenia (formerly known as Lek Pharmaceutical and Chemical Company, d.d.). (Doc. 35, PageId 1297). The micronized Gentamicin powder has a median particle size between 3.9 and 4.42 microns. (Doc. 35, PageId1297). The non-micronized Gentamicin powder has a median particle size of 7.67 microns and a mean particle size of 9.1 microns. (Doc. 35, PageId 1299).

**B. Origins of DePuy's Bone Cement**

Bone cement is regulated by the FDA under the Medical Device Amendments to the Food, Drug, and Cosmetic Act. (Doc. 29-4, PageId 265). DePuy 1 Bone Cement (the predicate device) was originally a Class III device, which is a device that raises new questions regarding safety and effectiveness and therefore requires more control. (Doc. 29-4, PageId 265). As a Class III device, DePuy 1 Bone Cement had to obtain Premarket Approval ("PMA") from the FDA. (Doc. 29-4, PageId 266). The DePuy 1 Bone Cement was approved by the FDA on February 11, 1997 through the Premarket Approval ("PMA") process as P9600001. (Doc. 29-4, PageId 267). Between February 1997 and May 1999, DePuy submitted, and the FDA approved, eight PMA supplements for DePuy 1 Bone Cement, which by then was known as DePuy 1, DePuy 3 and Endurance cements. (Doc. 29-4, PageId 268).

On October 14, 1999, the FDA issued an order reclassifying the PMMA bone cement from Class III (PMA) into Class II (special controls). (Doc. 29-4, PageId 268, 290; Doc. 41-2, PageId 1703). Class II devices must meet the general controls of Class I devices, as well as performance standards or other requirements as deemed necessary by the FDA. (Doc. 29-4, PageId 265). Premarket Notification under § 510(k) of the Act is required before Class II devices may be marketed. (Doc. 29-4, PageId 265). A document titled "Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA" ("Guidance Document") was issued with respect to the PMMA Bone Cements. (Doc. 29-4, PageId 291; Doc. 41-2, PageId 1700). The most recent version of the Guidance Document provided was issued on July 17, 2002. (Doc. 29-4, PageId 291; Doc. 41-2, PageId 1700).[1] The Guidance Document (one version of it) contains the following language prior to the introductory paragraph:

> *This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.*

(Doc. 41-2, PageId 1703). It indicates in the "Background" section that the "FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of PMMA bone cement." (Doc. 29-4, PageId 294). According to the Guidance Document, the scope "is currently limited to bone cement as described in 21 CFR 888.3027 (product code: LOD)." (Doc. 29-4, PageId 297; Doc. 41-2, PageId 1706). The Guidance Document (one version of it) indicates that "Alternate materials may be demonstrated to be substantially equivalent to PMMA used in bone cement.

[1] Two versions of the Guidance Document were presented to the Court. While they appear in material respects to be similar, they do appear to have some differences, which are noted herein where believed to be pertinent.

FDA will assign new product codes for bone cements formulated from alternate materials that are determined to be substantially equivalent under section 510(k) of the Act." (Doc. 29-4, PageId 297). While the Guidance Document suggests an Abbreviated 510(k) as the least burdensome means of demonstrating substantial equivalence for a new device, it also notes that "[m]anufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k)." (Doc. 41-2, PageId 1704). It then outlines the content and format of an Abbreviated 510(k) submission, the scope of the document, the risks to health, biocompatibility, recommendations for evaluating the material and performance characteristics of the final sterilized PMMA bone cement, guidance on evaluating the sterility of the device, suggested labeling, and information on clinical studies. (Doc. 41-2, PageId 1703-13). Among the identified risks to health is loosening of the prosthesis, which is identified in the following context:

> Inadequate fixation or unanticipated postoperative events may affect the cement-bone interface, and lead to micromotion of cement against bone surface. A fibrous tissue layer may develop between the cement and the bone, and the loosening of the prosthesis may occur leading to implant failure. Long-term follow-up is advised for all patients on a regularly scheduled basis.

(Doc. 41-2, PageId 1712). On September 29, 2003, the FDA granted 510(k) marketing approval through K023103 for DePuy's bone cement using micronized Gentamicin powder provided by Lek Pharmaceutical and Chemical Company. (Doc. 29-4, PageId 269).

On June 18, 2004, DePuy submitted a 510(k) premarket notification for its DePuy 1 Gentamicin Bone Cement to make a change in the Gentamicin from micronized to non-micronized particles. (Doc. 41-3, PageId 1716). The FDA granted marketing approval for DePuy 1 Gentamicin Bone Cement to use non-micronized Gentamicin on July 1, 2004, as K041656. (Doc. 29-4, PageId 270; Doc. 41-3, PageId 1716). The identified Device Product Code was LOD. (Doc. 41-3, PageId 1716).

On October 24, 2005, DePuy submitted a "Special 510(k): Device Modification" premarket notification for its DePuy 1 Bone Cement to make changes to its bone cement liquid formulation. (Doc. 41-4, PageId 170-21; Doc. 42, PageId 1763). The Special 510(k) does not reference the Guidance Document. (*See* Doc. 42). At this time, DePuy changed the name of the bone cement from DePuy 1 Gentamicin Bone Cement to DePuy CMW 1 Gentamicin Bone Cement. (Doc. 41-4, PageId 1720). On November 22, 2005, the FDA granted marketing approval for DePuy CMW 1 Gentamicin Bone Cement. (Doc. 41-4, PageId 1721). The identified Device Product Code was MBB. (Doc. 41-4, PageId 1720).

The polymer powder component of the DePuy CMW 1 Gentamicin Bone Cement contains 84.73% w/w of polymethyl methacrylate whereas the polymer component of the DePuy 1 Bone Cement contains 88.85% w/w of polymethyl methacrylate. (Doc. 29-4, PageId 274; Doc. 41-6, PageId 1726).

**C. Use of DePuy CMW 1 Gentamicin Bone Cement in Thompson's Surgery**

In January 2009, Thompson underwent a partial knee replacement surgery. (Doc. 42-1, PageId 1779). Her orthopaedic surgeon was Michael Swank, M.D., who averages about 400 primary knee replacements a year using bone cement in them almost exclusively. (Doc. 33, PageId 844-45). Approximately ten percent of those surgeries are partial knee replacements. (Doc. 33, PageId 853-54). Dr. Swank learned about cemented joint replacements during his residency. (Doc. 33, PaegId 845-46, 964-65). In his practice, he used DePuy 1 bone cement and he switched to CMW 1 Gentamicin Bone Cement when it came on the market in 2004. (Doc. 33, PageId 847-49). Dr. Swank described the CMW 1 Gentamicin Bone Cement as medium viscosity. (Doc. 33, PageId 862-63). Dr. Swank testified that he expected a typical replacement to last ten to twenty years. (Doc. 33, PageId 962-63).

Dr. Swank utilized DePuy's CMW 1 Gentamicin Bone Cement for Thompson's surgery, which contained non-micronized Gentamicin. (Doc. 33, PageId 870, 873-74; Doc. 41-1 PageId 1779). Her bone cement was Lot No. 2641175, 40 grams, which had been released from manufacturing for distribution in the United States on July 16, 2008. (Doc. 35, PageId 1298). The expiration date for the lot was May 2011. (Doc. 35, PageId 1298). Dr. Swank may have read the package insert for the bone cement early in his career, but he did not consult it in 2009 at the time of Thompson's surgery. (Doc. 33, PageId 874).

For Thompson's surgery, two 40-gram packages of CMW1 Gentamicin Bone Cement were vacuum mixed by Mike Barker, the scrub tech. (Doc. 33, PageId 870-71, 878). Dr. Swank could not say whether he observed Barker mixing the cement on the day of Thompson's surgery, but he testified that Barker was an accomplished, competent scrub tech with whom he had worked many times in the past and that he used the same surgical process and procedures he had used for knee replacements over the preceding seventeen years. (Doc. 33, PageId 879-80, 886). Dr. Swank testified that he did not observe any issue with the viscosity of the bone cement at the time of the surgery and that he did not recall a problem with the time it took for the bone cement to form a dough in the vacuum mixer. (Doc. 33, PageId 981, 992).

Thompson initially did well after her partial knee replacement surgery. (Doc. 32, PageId 662-63; Doc. 42-1, PageId 1780). In early 2011, she began having issues with pain and swelling in her knee. (Doc. 32, PageId 694-98; Doc. 42-1, PageId 1780). In or around April 2012, Thompson underwent a bone scan, which showed the tibial component of her knee replacement was loose. (Doc. 33, PageId 917-918). Dr. Swank testified that on the tibial portion of Thompson's knee replacement, the x-rays and bone scan showed a failure of the cement at the cement/bone interface. (Doc. 33, PageId 926; Doc. 42-1, PageId 1780). Dr. Swank testified that

he would not expect to see loosening of the cement within three years of surgery. (Doc. 33, PageId 982). He explained that with expected typical loosening, the loosening in one area progresses, but in Thompson's case there was complete radiolucency around the entire tibial component. (Doc. 33, PageId 982-83). He also noted that there was poor osteo integration of the cement into the bone. (Doc. 33, PageId 984). He therefore recommended that Thompson undergo revision surgery. (Doc. 33, PageId 918-21). On May 24, 2012, Dr. Swank performed knee revision surgery, using Stryker Simplex bone cement. (Doc. 33, PageId 918-21; Doc. 42-1, PageId 1780). At the time of the revision surgery, Dr. Swank found that the tibial component was completely loose, and the femoral component, which was still fixed along the inside of the medial condyle, was easily able to be removed. (Doc. 33, PageId 920). He noted in his operative report that, in addition to the failure at the cement/bone interface as shown on the x-rays and bone scan, there also was a failure at the cement/device interface. (Doc. 33, PageId 925-26).

On November 12, 2012, an x-ray showed radiolucency on the medial side of the Stryker Simplex cement mantle on Thompson's tibial component. (Doc. 33, PageId 999-1000). An April 30, 2014 x-ray also showed radiolucency on the medial side of her tibia. (Doc. 33, PageId 1000). Dr. Swank testified that radiolucency on an x-ray could be, but is not necessarily, a sign of loosening, and progressive radiolucencies and radiolucencies of a certain size are the ones that are disturbing. (Doc. 33, PageId 1002). Thompson's November 2014 x-ray did not show progression of radiolucency. (Doc. 33, PageId 1001-02).

Between 2008 and January 2015, DePuy received numerous adverse event reports of loosening of prosthetic devices cemented with CMW 1 Gentamicin Bone Cement. (Doc. 42-3).

**D. Plaintiff's Expert Testimony**

**2. Dr. Swank**

Dr. Swank testified as to the above facts concerning Thompson's surgery as well as to his opinions in this matter. He opined that the CMW 1 Gentamicin Bone Cement failed at both the cement/bone interface and the cement/implant interface. (Doc. 33, PageId 925-26). He further opined that the CMW 1 Gentamicin Bone Cement failed at a higher rate than expected and the risks of the products outweighed the benefits. (Doc. 42-1, PageId 1782).

Dr. Swank began using DePuy CMW 1 Gentamicin Bone Cement in 2004. (Doc. 33, PageId 847-49). Initially, he had a good experience with the cement. (Doc. 42-1, PageId 1781). In 2009, he began seeing failures of the cement in his patients. (Doc. 33, PageId 858). In 2009, two patients on whom Dr. Swank had performed total knee replacements on the same day in 2007 with the same lot of bone cement presented to him with loosening of their prosthetic knees. (Doc. 33, PageId 858). Dr. Swank was able to determine the timing and lot used in their primary surgeries because he participated in the DePuy Outcome Tracking System. (Doc. 33, PageId 858). Dr. Swank then contacted DePuy. (Doc. 33, PageId 896-97; Doc. 42-1, PageId 1781). In February 2010, representatives from DePuy met with Dr. Swank to address his concerns about cement failures. (Doc. 33, PageId 896-97; Doc. 42-1, PageId 1781). By the date of that meeting, Dr. Swank had seven patients on whom he performed surgery with DePuy bone cement who had experienced loosening of the device within two to three years after the primary surgeries. (Doc. 33, PageId 898). Dr. Swank performed revision surgery on many of those patients due to loosening of the prosthetic component and in each case the components became loose at the cement interface. (Doc. 42-1, PageId 1781). Dr. Swank testified that Thompson's cement failed in the same manner as those earlier reported cases. (Doc. 33, PageId 925-26).

As part of DePuy's investigation into the cement failures reported by Dr. Swank, representatives from DePuy examined the procedures undertaken by Dr. Swank and his surgical staff to prepare the cement for use in surgery. (Doc. 42-1, PageId 1781). DePuy was unable to identify any factors in Dr. Swank's surgical procedures or in his patients that would have caused the cement failures. (Doc. 42-1, PageId 1781). DePuy nonetheless re-educated Dr. Swank on the proper procedures to mix cement. (Doc. 33, PageId 899). Because DePuy was unable to identify anything wrong in Dr. Swank's surgical techniques, his surgical facilities, or his surgical staff's procedures in vacuum mixing the cement, Dr. Swank decided to cease using the DePuy CMW 1 Gentamicin Bone Cement and switched to Stryker Simplex bone cement for his patients. (Doc. 33, PageId 896-905; Doc. 42-1, PageId 1781-82). Since making the switch, Dr. Swank has had no further incidents of bone cement failure among his patients. (Doc. 42-1, PageId 1782).

**2. James Mason, Ph.D.**

Dr. Mason was retained as Thompson's bone cement expert in October 2014. (Doc. 24, PageId 1023). Dr. Mason has a B.S. from the University of California Berkeley in 1986; a Master of Science in Material Science and Engineering from the University of California Berkeley in 1988; a Ph.D. in Solid Mechanics with a Materials Science Minor from the California Institute of Technology in 1993; and a Professional Science Master's Degree in Biology from the Illinois Institute of Technology in 2011. (Doc. 34, PageId 1025-26; Doc. 41-8, PageId 1741). None of his coursework involved bone cements. (Doc. 34, PageId 1025-26).

Dr. Mason's professional employment is extensive. (*See* 41-8, PageId 1739-41). He formerly worked for Zimmer Orthopaedics, Inc., a competitor of DePuy, in various capacities. (Doc. 34, PageId 1068; Doc. 41-8, PageId 1740). Part of his work for Zimmer involved its bone cement, as he was involved in the effort to create an injectable implant that was based almost

entirely on bone cement. (Doc. 34, PageId 1069). He worked closely with a group performing and analyzing mechanical testing of the cements that were used in modified cements that they were trying to use. (Doc. 34, PageId 1069). Zimmer did not, however, make an antibiotic bone cement. (Doc. 34, PageId 1069).

After leaving Zimmer, Dr. Mason founded a start-up company developing fiber-reinforced bone cement without antibiotics, using Palacos R and Simplex P as a standard. (Doc. 34, PageId 1038, 1042). The product was never commercialized; the company encountered production problems and ran out of money before it could implement the testing for the quality system required by the FDA for a Section 510(k) application. (Doc. 34, PageId 1040-42). The fiber-reinforced bone cement project ended in 2010, and Dr. Mason abandoned the patent application related to the technology. (Doc. 34, PageId 1046).

Dr. Mason currently is a consultant with Rimkus Consulting. (Doc. 34, PageId 1061). Rimkus Consulting is a forensic engineering firm that provides analysis and opinions to its customers to help understand the cause of failures. (Doc. 34, PageId 1061). While he has worked on cases involving hip implant failures and a knee implant fracture, Thompson's case is his first bone cement case. (Doc. 34, PageId 1062).

Dr. Mason has published multiple peer-reviewed publications on issues involving biomechanics, biomaterials, and bone cement. (Doc. 34, PageId 1030-35). While none of his bone cement articles involved antibiotic bone cement or research on particle sizes of antibiotic powder in bone cement, he testified that antibiotic bone cements are not dramatically different from the bone cements on which he has worked. (Doc. 34, PageId 1035, 1048, 1077).

Dr. Mason opined that Thompson's implant loosened because the DePuy CMW 1 Gentamicin Bone Cement used in her surgery failed to properly affix the implant to the bone.

(Doc. 42-2, PageId 1806; Doc. 34, PageId 1179).[2] Dr. Mason indicated that orthopedic implant failures occur due to three basic groups of factors: (1) factors relating to the patient; (2) factors relating to the surgery; and (3) factors relating to the device. (Doc. 42-2, PageId 1807). On the first factor, he indicated that the record did not reflect that Thompson was not a compliant patient or that she contributed to the loosening of her implant. (Doc. 42-2, PageId 1807). He did not, however, speak or meet with Thompson directly to identify any potential patient-related factors. (Doc. 34, PageId 1142). On the second factor, he indicated that the documents as well as the report of Dr. Swank indicated that there was no indication that surgical factors contributed to the loosening. (Doc. 42-2, PageId 1807). He therefore focused his report on the third factor, considering the implant and materials used. (Doc. 42-2, PageId 1807). In doing so, Dr. Mason was unable to rely upon an inspection of the removed knee components or the actual bone cement, as neither was saved after the revision surgery. (Doc. 34, PageId 1110, 1116-17, 1153-54).[3]

He opined that, based on his experience and review of the DePuy documents, the viscosity of the DePuy bone cement changed after non-micronized gentamicin was introduced, first being too low and then, after corrections were made to the formulation, eventually becoming too high requiring a deviation from the manufacturing specifications. (Doc. 42-2, PageId 1806). He further opined that it is more likely than not that the viscosity and curing behavior was defective due to the use of non-micronized gentamicin sulfate in the DePuy CMW 1 Gentamicin Bone Cement. (Doc. 42-2, PageId 1806). While he acknowledged that adding any antibiotic to

[2] Dr. Mason testified that it was "not necessarily" his conclusion that the bone cement never affixed the implant to the bone. (Doc. 34, PageId 1179).

[3] Dr. Mason acknowledged that polyethylene wear debris also is recognized as an indirect cause of cement loosening. (Doc. 34, PageId 1150). He did not make any determination as to whether the polyethylene wear debris contributed to the loosening in this case, indicating that he gave it a low priority due to the timing of the loosening and knowledge that polyethylene performs pretty well. (Doc. 34, PageId 1151-52).

bone cement reduces its static and fatigue strength by 10 percent, regardless of whether the antibiotic powder is micronized or non-micronized, he also explained that the change from micronized to non-micronized particles made the Gentamicin particles larger in size and made the variation in the size of the Gentamicin particles larger. (Doc. 34, PageId 1053, 1054-55; Doc. 42-2, PageId 1808). According to Dr. Mason, both the average size and the variation in size of the Gentamicin powder can have a significant effect on the viscosity during cement curing. (Doc. 42-2, PageId 1808). He states that DePuy changed the polymer powder after marketing began in response to predictable thinning, which made the curing viscosity too thick. (Doc. 42-2, PageId 1809). DePuy then sought a deviation in the manufacturing process of CMW 1 Gentamicin Bone Cement. (Doc. 42-2, PageId 1809). Dr. Mason explained that the deviation showed that DePuy's response to problems with thin cements resulted in cements that were too thick. (Doc. 42-2, PageId 1809). He indicated that the deviation included the lot number for Thompson's powder, which is Lot No. 2610577. (Doc. 42-2, PageId 1809). Dr. Mason testified that DePuy tweaked the plastic powder without Gentamicin added to bring it back into specification. (Doc. 34, PageId 1197).

Some evidence shows that the pour tests considered by Dr. Mason used two powder lots with Gentamicin, which included Thompson's lot, as well as two powder lots without Gentamicin. (Doc. 35, PageId 1299, 1301). DePuy contends that the documents reflect that it knew that gamma sterilization would lower cement viscosity such that it approved the four powder blend lots for gamma sterilization with subsequent monitoring and approvals. (Doc. 35, PageId 1301). After the four gamma-sterilized powder lots were mixed with the liquid monomer that accompanies the finished powder component, all four lots passed. (Doc. 35, PageId 1301). After further testing, three of the four met in-process quality specifications. (Doc. 35, PageId

1301). One of the powder lots without Gentamicin failed that final test and was scrapped. (Doc. 35, PageId 1302).

With respect to the pour testing of the cements, Dr. Mason indicated that only a sample of each lot is tested. (Doc. 42-2, PageId 1810). According to Dr. Mason, if a lot barely passed testing, then it is possible and not unlikely that other samples would not have passed, given the inherently variability of the manufacturing and mixing of the material in the operating theater. (Doc. 42-2, PageId 1810). He concludes that based upon the destructive nature of the pour test as well as the high rate of product failures noted in the Manufacturer and User Facility Device Experience (MAUDE) database, it is most likely that some cements shipped with unacceptably high viscosity and handling characteristics. (Doc. 42-2, PageId 1810). He indicated that a surgeon may not have known that the cement had passed the workability phase during implantation if the set time varied significantly from lot to lot for the bone cement. (Doc. 42-2, PageId 1811).

Evaluating the MAUDE database, he indicated a high rate of loosening by DePuy CMW 1 Gentamicin Bone Cement since 2005. (Doc. 42-2, PageId 1812). He concludes that the government data indicates that DePuy CMW 1 Gentamicin Bone Cements result in loosening 20-60 times the rate of comparable cements. (Doc. 42-2, PageId 1812). He acknowledges, however, that there are some limitations to the MAUDE data and that the FDA has cautioned against using MAUDE data alone to establish rates of events, evaluate a change in events rates over time, or compare event rates between devices. (Doc. 34, PageId 1132-33). He also conceded that he is unaware whether Palacos or Simplex P used micronized or non-micronized Gentamicin and Tobramycin, respectively, and is unaware of the antibiotic particles sizes in those cements. (Doc. 34, PageId 1052-54).

In addition to the MAUDE data, Dr. Mason considered the operative notes of Dr. Swank, which he indicated are consistent with the viscosity being too high, voids forming on the cement/implant interface due to high viscosity, and the curing being unpredictable and the cement hardening before implant insertion. (Doc. 42, PageId 1812). He noted that there was no reason to believe from the record that the surgery contributed to the loosening or that Thompson was not a compliant patient. (Doc. 42-2, PageId 1807).

He therefore opined to a reasonable degree of scientific certainty that the DePuy CMW 1 Gentamicin Bone Cement used in Thompson's surgery was defective in design and manufacturing. (Doc. 42-2, PageId 1812). He further opined that the risks of DePuy CMW 1 Gentamicin Bone Cement outweighed the benefits, and a feasible alternative design—such as Palacos R + G or Simplex P—existed that could have been used in Thompson's surgery. (Doc. 42-2, PageId 1813).

## II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is "genuine" when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is "material" only if its resolution affects the outcome of the suit. *Id.*

On summary judgment, a court must view the evidence and draw all reasonable inferences in favor of the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The moving party has the burden of showing an absence of evidence to support the nonmoving party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

Once the moving party has met its burden of production, the nonmoving party cannot rest on his pleadings, but must present significant probative evidence in support of his complaint to defeat the motion for summary judgment. *Anderson*, 477 U.S. at 249. "The mere existence of a scintilla of evidence in support of the [nonmoving party's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmoving party]." *Id.* at 252. Entry of summary judgment is appropriate "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322.

## III. LEGAL ANALYSIS

Thompson alleged five causes of action against DePuy in the Complaint: (1) strict products liability for defective manufacturing under Ohio Rev. Code § 2307.74; (2) strict products liability for design defects under Ohio Rev. Code § 2307.75; (3) strict products liability for defect due to inadequate warning under Ohio Rev. Code § 2307.76; (4) strict products liability for defect due to nonconformance with representations under Ohio Rev. Code § 2307.77; and (5) fraudulent and negligent misrepresentation. Thompson also sought punitive damages against DePuy. Thompson has chosen not to proceed on the third claim and the fifth claim, and also has acknowledged that her allegations as to violations of federal requirements governing good manufacturing practices and device design need not be addressed. Accordingly, the following analysis will address only the first, second, and fourth claims, as well as the request for punitive damages.

### A. Preemption of Claims

DePuy contends that Thompson's claims are barred by federal preemption for two reasons. First, the CMW 1 Gentamicin Bone Cement is governed by the FDA's Special

Controls, which have a preemptive effect. Second, Dr. Mason speculated that the FDA mistakenly determined that DePuy CMW 1 Gentamicin Bone Cement with non-micronized Gentamicin is substantially equivalent to DePuy 1 Bone Cement with micronized Gentamicin, and such second-guessing is preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Thompson responds that the claims are not preempted by federal law because the medical device at issue was approved through the 510(k) process rather than PMA process and that DePuy cannot bootstrap the CMW 1 Gentamicin Bone Cement on the prior PMA approval due to the significant changes in the device since that original approval. She further contends that the general and special controls applicable to DePuy's bone cement do not impose any specific requirements which would address her claims. As for DePuy's contention that her claims are preempted under *Buckman*, Thompson argues that DePuy improperly characterizes the testimony it uses to support that argument.

DePuy replies that Thompson has not shown that the CMW 1 Gentamicin Bone Cement is deprived of preemption protection. It claims that she has presented no evidence that the addition of micronized Gentamicin and later non-micronized Gentamicin was a significant change. Further, it argues that the Class II Special Controls for the bone cement are specific and provide a basis for federal preemption.

**1. Express Preemption pursuant to 21 U.S.C. § 360k(a)**

The Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") contain a provision that expressly preempts some state and local causes of action regarding medical devices. It provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is

> different from, or in addition to, any requirement applicable under this Act [21 U.S.C. §§ 301 et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 U.S.C. §§ 301 et seq.].

21 U.S.C. § 360k(a). The FDA's regulations further explain, in pertinent part:

> (d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act: . . . (2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act. . . . Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

21 C.F.R. § 808.1(d).

DePuy argues that all of Thompson's claims are preempted as a result of the PMA approval on February 11, 1997. The Court disagrees. The CMW 1 Gentamicin Bone Cement at issue here was approved through the 510(k) process instead of the PMA process due to the reclassification of bone cement to a Class II device with Special Controls on October 14, 1999. DePuy has not cited a single case that would permit it to piggyback on the prior PMA approval after having undergone several changes and approvals to the medical device through the 510(k) process. While the case cited by Thompson, *Rousseau v. DePuy Orthopaedics, Inc.*, No. 06-0517, 2006 U.S. Dist. LEXIS 90331, at *26-27 (W.D. La. Dec. 13, 2006), indicates that medical devices previously approved through the PMA process that are subsequently reclassified do not

automatically lose preemption protection, that case, unlike this case, involved a medical device that had undergone no changes and had not had any subsequent changes approved through the 510(k) process. Here, there is no indication that the PMA process considered, evaluated, or even addressed the safety or efficacy of micronized or non-micronized Gentamicin or any other specific requirements that are distinctively related to the design or manufacture of the CMW 1 Gentamicin Bone Cement.

DePuy's next argument is that the special controls on its product set forth in the FDA Guidance Document titled "Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA" warrant preemption of Thompson's claims. The FDA typically does not establish a "requirement" for a medical device when it only approves the device pursuant to a "substantial equivalence" exception to the premarket approval process "because the 510k process is focused on *equivalence*, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996). Special control documents may provide specific requirements, however, that support a conclusion of preemption of state law claims. But those specific requirements must show that "the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Medtronic*, 518 U.S. at 501. In each of the cases relied upon by DePuy that involved special controls or a guidance document, the "requirement" promulgated by the FDA was a detailed and specific mandate. In *Degelmann v. Advanced Medical Optics, Inc.*, 659 F.3d 835, 841-42 (9th Cir. 2011), *vacated and appeal dismissed by*, 699 F.3d 1103 (9th Cir. 2012), the circuit court examined preemption in the context of whether contact lens solution was

mislabeled as "disinfecting solution." The FDA had issued a document containing special controls for when a contact lens solution could be labeled a "disinfecting solution." *Id.* The regulation specifically required that a solution meet standalone performance criteria for disinfecting contact lens products to be labeled "disinfecting solution." *Id.* The circuit court found that regulation to be a specific requirement that the defendant had undisputedly satisfied and that the state consumer protection and false advertising claims would impose a requirement in addition to or different from the FDA requirement. *Id.* at 842. Similarly, in *Tuttle v. CIBA Vision Corp.*, Case No. 2:05-cv-340, 2007 U.S. Dist. LEXIS 14676, at *6-7 (D. Utah Mar. 1, 2007), the district court found a claim arising out of a warning defect was preempted under § 360k where it was "undisputed that the FDA has issued a comprehensive Guidance Document which governs the form, content, and requirements for labels" on the products such as the one at issue in that case. It also was undisputed that the FDA reviewed and approved the language in the defendant's warnings, instructions, and package inserts for the product and that the defendant complied with the FDA's requirement. *Id.* at *6.[4]

Here, DePuy has cited to the following language to support the argument that the guidance document should preempt all of Thompson's state law claims: "FDA believes that special controls, when combined with general controls, will be sufficient to provide reasonable

[4] The other cases relied upon by DePuy involved requirements set forth in the Code of Federal Regulations. In those cases, however, the regulations found to preempt a state law claim provided a detailed and specific mandate. *See Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir. 1997) (tampon regulations promulgated in 21 C.F.R. § 801.430 that mandated the specific substantive content of the warning in regards to both the product and the disease at issue preempted state tort claims for failure to warn); *Busch v. Ansell Perry, Inc.*, Case No. 3:01-cv-126, 2005 U.S. Dist. LEXIS 44075 (W.D. Ky. Mar. 8, 2005) (because the Code of Federal Regulations required specific language be included in a warning with respect to a specific group of devices to which the defendant's latex gloves belong and such language was indeed included by the defendant on its product, the failure to warn claim was preempted); *Berger v. Personal Prods., Inc.*, 797 P.2d 1148, 1150 (1990) (similar to *Papike*, tampon labeling requirements in 21 C.F.R. § 808.1(b) preempted state tort law claim on tampon labeling and warnings for toxic shock syndrome).

assurance of the safety and effectiveness of PMMA bone cement." (Doc. 41-2, PageId 1703). But DePuy has provided no persuasive arguments that the language itself renders the guidance document in its entirety a "requirement" in a manner similar to PMMA approval. DePuy relies on the following language in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) for its position that the statement reflects the same assurances as the PMA process:

> While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence. While devices that enter the market through § 510(k) have never been formally reviewed under the MDA for safety or efficacy, the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness.

(internal quotations and citations omitted). DePuy theorizes that because the FDA sets forth guidelines that it believes provides a reasonable assurance of safety and effectiveness, the 510(k) process with special controls is sufficiently equivalent to the PMA process to warrant preemption. That argument is flawed.

There is no evidence provided to the Court that would demonstrate that the 510(k) approval process, even with special controls, is equivalent to that provided by the PMA process. As explained in *Medtronic*, the PMA process requires manufacturers to submit "detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." 518 U.S. at 477. In contrast, "the § 510(k) review is completed in an average of only 20 hours." *Id.* at 479. Even with the special controls, there is no evidence before the Court that would indicate the review for safety and efficacy in the § 510(k) process is comparable to that of the PMA process.

Moreover, the guidance document, while certainly providing important recommendations for the submissions under the 510(k) process, does not *mandate* any particular performance standards relating to, for example, the particle size, variation in particle size, viscosity.

Suggesting otherwise is the following language contained at the beginning of the guidance document:

> *This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.*

(Doc. 41-2, PageId 1703). Even the labeling section, the most specific section therein, does not mandate any particular language or warning. Instead, it provides "suggestions" for language to assist in preparing labeling that satisfies the requirements of 21 C.F.R. § 807.87(e), which provides that each premarket notification submission shall contain "Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use." (Doc. 41-2, PageId 1711).[5] DePuy has not pointed to any specific detailed language that mandates anything from the manufacturers or producers. All of the language instead is directed mostly to what needs to be submitted to the FDA to facilitate review of the 510(k) application. The statements therein thus are insufficient to qualify as specific "requirements" that preempt Thompson's state law claims.[6]

Finally, DePuy has not argued, and therefore has not demonstrated, that any state requirement is different from, or in addition to, any requirement applicable under the MDA.

[5]The inadequate warning claim, however, has been abandoned.

[6] Although the issue was not raised by the parties, it also is not entirely clear to the Court that the guidance document governs this particular device, i.e., the DePuy CMW1 Gentamicin Bone Cement used in Thompson's January 2009 operation. The guidance document provided by the parties limits its scope to product code LOD. (*See* Docs. 29-4, PageId 297; Doc. 41-2, PageId 1706). While the product code listed for the June 2004 510(k) for DePuy 1 Gentamicin Bone Cement is LOD (Doc. 41-3, PageId 1716), the product code listed for the October 2005 510(k) for DePuy CMW 1 Gentamicin Bone Cement is MBB (Doc. 41-4). While recognizing that both 510(k)'s refer to 21 C.F.R. § 888.3027, which, in turn, refers to the guidance document, the expressed limited scope of the guidance document to product code LOD presents a material issue concerning its application to the particular device.

Accordingly, the Court lacks a sufficient basis upon which to conclude that Thompson's state law claims are preempted by the prior PMA approval or the Guidance Document.

**2. Implied Preemption under *Buckman Co. v. Plaintiffs' Legal Committee***

In *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 343 (2001), patients who claimed injuries resulting from the use of orthopedic bone screws in the pedicles of their spines sued a consulting company that assisted the screw manufacturer in obtaining approval from the FDA for the use of the screws. The patients alleged that the consulting firm made fraudulent representations to the FDA as to the intended use of the bone screws, which resulted in improper market clearance and, ultimately, the patients' injuries. *Id.* The Supreme Court held that the fraud-on-the-FDA claims were impliedly preempted by the FDCA, as amended by the MDA. *Id.* at 344.

Unlike in *Buckman*, the claims in this case are not direct fraud-on-the-FDA claims.[7] Nor does DePuy present any evidence that Thompson premises her claims for manufacturing defect, design defect, and failure to conform with representations claims on the theory that DePuy committed fraud on the FDA. The sole excerpt of Dr. Mason's testimony upon which it bases its entire argument was given upon prompting from counsel for DePuy about substantial equivalence and is not an opinion given by Dr. Mason in his expert report. DePuy has not shown how or to what extent Thompson's claims rest upon that excerpt of his testimony. Moreover, the 510(k) process is one focused on equivalency rather than safety. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008).

[7] The application of *Buckman* to the request for punitive damages is addressed separately *infra*.

Accordingly, the Court finds that DePuy has not shown that Thompson's claims are preempted under *Buckman*.[8]

**B. Defective Manufacturing under Ohio Rev. Code § 2307.74 (Count One)**

Thompson brings the claim for strict products liability for defective manufacturing under Ohio Rev. Code § 2307.74. Section 2307.74 provides:

> A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

Ohio Rev. Code § 2307.74.

DePuy moves for summary judgment on this claim on the basis that the following testimony of Thompson's bone cement expert is insufficient to support a manufacturing defect claim: "I just don't have enough information about the manufacturing process" to render an opinion of defect and "I didn't rule a manufacturing problem." (Doc. 29-1, PageId 220) (quoting Doc. 34, PageId 1266).

Thompson responds that Dr. Mason's testimony on deviation from performance standards creates a genuine issue of material fact as to whether DePuy's bone cement failed to properly affix the prosthesis to Thompson's living bone.

In its reply, DePuy first raises a new argument—that it is the distributor, not the manufacturer, and cannot be liable for a manufacturing defect. Next, it argues that there is no evidence that CMW 1 Gentamicin Bone Cement deviated in a material way from the design specifications, formula, or performance standards of the manufacturer. DePuy argues that

[8] If the case proceeds to trial, the Court may monitor arguments and evidence presented to ensure they do not run afoul of *Buckman*.

Thompson's reliance on her expert's offhand comment that he did not "rule out" the possibility of a manufacturing issue is not evidence of a manufacturing defect. It further argues that circumstantial evidence is insufficient where it provides only one possible inference, that she failed to present any evidence her tibial tray would not have loosened after three years if it had been properly manufactured, or that the CMW 1 Gentamicin Bone Cement deviated from any particular performance standards of its manufacturer, DePuy International Ltd., which is not a defendant here.

Upon review, the Court finds sufficient circumstantial evidence of a manufacturing defect to preclude summary judgment.[9] "[I]t is well-settled that the existence of a manufacturing defect may be established by circumstantial evidence." *Pearce v. Fouad*, 146 Ohio App. 3d 496, 504 (Franklin Cnty. 2001) (citing *Colboch v. Uniroyal Tire Co., Inc.*, 108 Ohio App. 3d 448 (Cuyahoga Cnty. 1996)); *see also* Ohio Rev. Code § 2307.73(B). In this case, Dr. Mason opined that the bone cement failed to properly affix the prosthesis to Thompson's living bone, which resulted in the need for revision surgery approximately three years after her original surgery. Both Dr. Mason and Dr. Swank testified that the implant replacement typically is expected to last within the range of ten to twenty years. Dr. Swank testified that failure within three years is atypical, that he had several patients who had similar loosening with CMW 1 Gentamicin Bone Cement, and that since switching to another bone cement he has had no further incidents of similar bone cement loosening among his patients.

[9] The Court need not address DePuy's argument that it is not the manufacturer, as issues raised for the first time in a reply brief are deemed waived. *See Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 553 (6th Cir. 2008); *Tonguette v. Sun Life & Health Ins. Co. (U.S.)*, No. 2:12-cv-00006, 2013 U.S. Dist. LEXIS 60716, at *11-12 (S.D. Ohio Apr. 29, 2013). Moreover, consistent with the Court's Opinion and Order on DePuy's motion to dismiss, the Court recognizes that "suppliers" may be liable under the OPLA, as if they were manufacturers, under certain circumstances. Ohio Rev. Code § 2307.78(B).

Dr. Mason also testified as to three general factors that lead to loosening of bone cement: (1) factors relating to the patient; (2) factors relating to the surgery; and (3) factors relating to the device. He explained why he ruled out and/or did not consider relevant multiple of the potential causes, including patient non-compliance, commorbities, the mixing technique, infection, tray fracture, and polyethylene wear debris. Dr. Swank's testimony is consistent.

Dr. Mason testified that he did not rule out a manufacturing defect except as to the pour testing issues. (Doc. 34, PageId 1266, 1284). He also testified that he was sufficiently familiar with the bone cement manufacturing process to know the issues that arise and how they interplay with bone cement properties, and he explained why he believed the change to non-micronized gentamicin affected the powder's particle size and the particle size distribution, altering the viscosity and the curing behavior of the cement. (Doc. 34, PageId 1078, 1080-81, 1186-87). While Dr. Swank did not observe viscosity issues at the time of the original surgery, Dr. Mason explained that the effect on the viscosity may be imperceptible and still change the curing behavior. Further, Dr. Swank confirmed that the timing of the loosening was accelerated and that the pattern of the loosening that he observed on the x-ray appeared to him to be atypical or accelerated.

On the whole, the evidence presented by Thompson constitutes sufficient circumstantial evidence upon which a jury could find a defect present in the bone cement when it left the manufacturer, without which alleged defect the injury to Thompson would not have occurred. *See Jones v. Staubli Motor Sports Div. of Staubli Am. Corp.*, 897 F. Supp. 2d 599, 610-11 (S.D. Ohio 2012); *Miller v. Alza Corp.*, 759 F. Supp. 2d 929, 941-42 (S.D. Ohio 2010); *Pearce v. Fouad*, 146 Ohio App. 3d 496, 504 (Franklin Cnty. 2001).

**C. Strict Products Liability for Design Defects under Ohio Rev. Code § 2307.75 (Count Two)**

Thompson brings the claim for strict products liability for defective design under Ohio Rev. Code § 2307.75. Section 2307.75 provides, in pertinent part:

> [A] product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation . . . .

Ohio Rev. Code § 2307.75(A). That section further sets forth factors to be considered in balancing the foreseeable risks and the benefits associated with the design or formulation. Ohio Rev. Code § 2307.75(B)-(C). Yet, there are some specifically articulated instances in which a product cannot be defective in design or formulation. *See* Ohio Rev. Code § 2307.75(D), (E), (F).

DePuy moves for summary judgment on this claim on the grounds that (1) Thompson lacks evidence—expert or otherwise—on the change in the liquid formulation having any effect on the bone cement and (2) Dr. Mason's opinion as to the change and micronized to non-micronized Gentamicin powder are based on guesswork, speculation, a misinterpretation of the manufacturing documents for Thompson's bone cement, and a misuse of the FDA's MAUDE database such that he is not qualified under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), to testify to scientific knowledge that would assist the trier of fact.

Thompson responds that DePuy improperly seeks a *Daubert* determination in the context of summary judgment and any issues raised go to the weight rather than credibility of his opinions. Thompson insists that she has presented sufficient evidence of a design defect, namely, the opinions of Dr. Swank and Dr. Mason.

DePuy replies that Thompson mistakenly assumed that her design defect claim is subject to the risk/benefits test because an adequate warning is a complete defense to a design defect claim for such prescription medical devices under Ohio Rev. Code § § 2307.75(D). DePuy

reasons that because Thompson abandoned her claim for inadequate warning, she has conceded that appropriate warnings accompanied the CMW 1 Gentamicin Bone Cement. Further, DePuy argues that a *Daubert* determination is appropriate in the context of summary judgment and that the Court should find Thompson has failed to present admissible, qualified expert testimony necessary to sustain a claim for design defect.

Starting with the change in the liquid formulation, the Court agrees with DePuy that Thompson has presented no evidence—expert or otherwise—that could show that a defect relating to the liquid formulation. Thompson provides no argument as to this issue in her opposition brief. As such, summary judgment shall be granted to DePuy as to the design defect claim resting upon this theory.

As for the change from micronized to non-micronized particles, the Court starts with the *Daubert* issue. The Federal Rules of Evidence provide:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The Court's gatekeeping role under Rule 702 requires it to determine the relevance and reliability of all expert testimony. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999); *Daubert*, 509 U.S. 579. In *Daubert*, the Supreme Court set out a non-exhaustive list of factors to consider in determining whether specific scientific testimony is reliable. *Daubert*, 509 U.S. at 593-94. These include whether the theory or technique can be

(and has been) tested; whether the theory or technique has been subjected to peer review and publication; the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation; and the extent to which the theory or technique has been accepted in its field. *See id.* Yet, "the test of reliability is flexible, and *Daubert's* list of specific factors neither necessarily nor exclusively applies to all experts or in every case." *Kumho Tire*, 526 U.S. at 141. The reliability of an expert opinion should not be confused with its credibility and accuracy. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008). "[A] determination that proffered expert testimony is reliable does not indicate in any way, the correctness or truthfulness of such an opinion." *Id.* "Instead, the requirement that an expert's testimony be reliable means that it must be supported by appropriate validation—i.e., good grounds based on what is known." *Id*. (citing *Daubert*, 509 U.S. at 590). "The task for the district court in deciding whether an expert's opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation." *Id.* at 529-30. "But 'rejection of expert testimony is the exception rather than the rule,' and we will generally permit testimony based on allegedly erroneous facts when there is some support for those facts in the record." *Id.* at 530 (quoting Fed. R. Evid. 702, Advisory Comm. Comment, 2000 amend.).

While a court may make a *Daubert* determination on the truncated record presented at summary judgment, it should do so cautiously and only in the most clear-cut of cases. *Cortes-Irizarry v. Corporacion Insular De Seguros*, 111 F.3d 184, 188 (1st Cir. 1997). The "summary judgment process does not conform well to the discipline that *Daubert* imposes[.]" *Id.* Thus, a "trial setting normally will provide the best operating environment for the triage which *Daubert* demands." *Id.*

Here, DePuy has not moved to exclude the testimony of Dr. Mason wholesale, claiming that it is so unreliable that it cannot support a single claim brought by Thompson. Instead, DePuy has moved to exclude the testimony only with respect to the defective design claim. To rule on the reliability of Dr. Mason's testimony in the context of only a single claim would be short sighted, ignoring the reliability of the testimony as a whole and in regards to the other claims raised in this litigation. Additionally, the Court does not find that this is a "clear cut" case where such a premature ruling is necessary or appropriate. Many of DePuy's arguments challenge the accuracy of Dr. Mason's interpretation of the factual evidence. But any purported inaccuracies do not necessarily render his testimony unreliable. More information than that which has been presented on the truncated record of the summary judgment motion is necessary to make this determination. Further, the challenges as to Dr. Mason's qualifications and his conclusions on viscosity and curing behavior are subject to factual disputes that are more appropriately reserved for the trial setting. While DePuy certainly has identified potentially serious flaws in Dr. Mason's testimony, it has not presented a clear-cut case that Dr. Mason's testimony as a whole is unreliable or that he plainly lacks the necessary qualifications to render such an opinion. The Court therefore declines to make a *Daubert* ruling in the context of this summary judgment motion.

The next issue for the Court to consider is whether Thompson has presented a genuine issue of material fact as to a design defect based on the change to non-micronized particles. Dr. Swank testified that the cement around the tibial component of Thompson's knee failed at both the cement/bone interface and the cement/device interface. Dr. Swank further testified that there was poor osteo integration of the cement to the bone. Dr. Swank found nothing Thompson did to contribute to the failure to the cement and that DePuy's own investigation found nothing amiss

with his process and procedure for mixing cement or using cement for his joint replacement surgeries. He further indicated that from 2004 through approximately 2009 he had relatively few complications related to the use of bone cement, but that between 2009 and 2010, he had multiple patients who had surgery in which he used DePuy CMW 1 Gentamicin Bone Cement who had loosening of the prosthetic components due to a bone cement failure at the cement interface. After an unsatisfactory failure investigation by DePuy in 2010, Dr. Swank switched from the use of DePuy CMW 1 Gentamicin Bone Cement to Simplex with Tobramycin. He reports that he has had no further incidents of bone cement failure among his patients since making the switch. Based upon his education, training, and experience, he opines that the CMW 1 Gentamicin Bone Cement failed at a higher than expected rate for bone cement and that FDA adverse event reports likewise show a higher reported complication rate than either Palacos or Simplex, which is consistent with his experience.

Dr. Mason, relying in part on the report of Dr. Swank, as well as his education, knowledge, experience, and review of the DePuy documents, opined that the viscosity and curing behavior of the cement was defective due to the use of non-micronized Gentamicin. He explained that the change to non-micronized Gentamicin was intended to "enhance the elution rates" of CMW cements with gentamicin sulfate and to "bring them in line with Palacos R with gentamicin." (Doc. 42-2, PageId 1808).[10] According to Dr. Mason, that change had the following two effects: (1) the Gentamicin particles became larger in size and (2) the variation in the size of the Gentamicin particles became larger. He explained how both those factors can have a significant effect on the viscosity during cement curing. He further offered some indications, including the Deviation Report, that could suggest difficulties with obtaining the

[10] Generally, this appears consistent with the Harris Declaration, which indicates that the change from micronized to non-micronized particles was intended to improve the release of the antibiotic. (Doc. 29-4, PageId 270).

correct viscosity. Dr. Mason further explained that "only a sample of each lot is tested" and that "[i]f the lot barely passed testing, it is possible and not unlikely other samples would not have passed, given the inherent variability of the manufacturing and mixing of the material in the operating theater." (Doc. 42-2, PageId 1810). He stated that unpredictable curing and viscosity issues were noted following the change to non-micronized gentamicin particles and that such unpredictable curing and viscosity could result in a lack of fixation. He noted that Dr. Swank's operative note for Thompson's May 2012 revision surgery supported his opinions. There is no indication that product users were given any warning that there is a significant risk of early loosening as a result of the use of the CMW 1 Gentamicin Bone Cement, even though they may have some general knowledge that loosening could occur with the use of bone cements.[11] Dr. Mason therefore opined that the CMW 1 Gentamicin Bone Cement used in Thompson's surgery was defective in design and that the risks outweighed the benefits. (Doc. 42-2, PageId 1813). While Thompson's expert testimony and evidence may be vigorously challenged and may even be undermined at trial, the Court finds that when the evidence is construed in the light most favorable to Thompson, it sufficiently raises genuine issues of material fact as to whether the risks outweigh the benefits under Ohio Rev. Code § 2307.75(B)-(C) to survive summary judgment.

Finally, the Court does not find that DePuy has demonstrated that Ohio Rev. Code § 2307.75(D) applies to bar the claim against it. Section 2307.75(D) provides:

> An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate

[11] While DePuy notes that the FDA observed in the Special Controls for PMMA bone cement that "[l]oosening or displacement of the prosthesis" is among "the most frequent adverse reactions reported with acrylic bone cements" (Doc. 45, PageId 1890), there is nothing indicating that any such warning was provided to product users or consumers. In any event, that statement does not reflect the risk of premature loosening, particularly within three years from the time of the surgery.

> warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect.

Ohio Rev. Code § 2307.75(D). "Unavoidably unsafe" means "that, in the state of technical, scientific, and medical knowledge at the time a product in question left the control of its manufacturer, an aspect of that product was incapable of being made safe." Ohio Rev. Code § 2307.71(A)(16).

Contrary to DePuy's argument, which was raised for the first time in its reply brief,[12] not all prescription medical devices are deemed unavoidably unsafe. Rather, consistent with the statutory definition of "unavoidably unsafe," the Supreme Court of Ohio held that "a product is unavoidably unsafe if, at the time of its distribution, there existed no alternative design which would have as effectively accomplished the same purpose or result with less risk." *See White v. Wyeth Laboratories, Inc.*, 40 Ohio St. 3d 390 (1988); *see also Miller v. Alza Corp.*, 759 F. Supp. 2d 929, 940 (S.D. Ohio 2010). DePuy has not demonstrated that there is no genuine issue of material fact to whether the CMW 1 Gentamicin Bone Cement was unavoidably unsafe in such a manner. Nor has DePuy cited a single case in which a similar product has been found to be unavoidably unsafe. As such, summary judgment is not appropriate on this basis.

### D. Strict Products Liability for Defect Due to Nonconformance with Representations under Ohio Rev. Code § 2307.77 (Count Four)

Thompson brings the claim for strict products liability based upon non-conformance with representations under Ohio Rev. Code § 2307.77. Section 2307.77 provides:

> A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even

[12] Thompson therefore did not have an opportunity to respond to this argument, and issues not raised for the first time in a reply brief are deemed waived. *See Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 553 (6th Cir. 2008); *Tonguette v. Sun Life & Health Ins. Co. (U.S.)*, No. 2:12-cv-00006, 2013 U.S. Dist. LEXIS 60716, at *11-12 (S.D. Ohio Apr. 29, 2013).

> though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

Ohio Rev. Code § 2307.77. To recover under this section, a plaintiff must prove that: (1) the defendant made a representation as to material fact concerning the character or quality of the product; (2) the product failed to conform to that representation; (3) justifiable reliance on that representation; and (4) the reliance on the defendant's representations was the direct and proximate cause of the plaintiff's injuries. *Cervelli v. Thompson/Center Arms*, 183 F. Supp. 2d 1032, 1045 (S.D. Ohio 2002); *see also Krumpelbeck v. Breg, Inc.*, 491 F. App'x 713, 722 (6th Cir. 2012).

DePuy argues that Thompson lacks evidence of all of the required elements. Specifically, it claims that there is no evidence of an express representation on which Dr. Swank or Thompson relied because Dr. Swank's choice of bone cements was not based upon a representation in the CMW 1 Gentamicin Bone Cement package and Dr. Swank did not tell Thompson he was using bone cement for her surgery.

Thompson responds that its 510(k) submission represented that its cement "is a self-curing cement" and "allows for the seating and securing of a metal or plastic prosthesis to living bone." She further indicates that the Instruction Leaflet represented that the bone cement is "used for securing a metal or polymeric prosthesis to living bone in arthroplasty procedures" and its bone cement "has no intrinsic adhesive properties, but rely instead on close mechanical interlock between the irregular bone surface and the prosthesis." Thompson contends that DePuy's cement failed to conform to those representations because the cement failed to properly affix Thompson's device to her bone. With respect to reliance, she considers Dr. Swank's testimony as indicating that "at some point, Dr. Swank likely possessed knowledge of the contents of the package insert" and that he expected the cement to last longer than three years.

She also emphasizes that whether Dr. Mason testified to nonconformance is irrelevant because he cannot testify what Dr. Swank knew or relied upon.

In its reply, DePuy argues for the first time that it is not the manufacturer and therefore cannot be liable. It also contends that the assertion that Thompson has no evidence of an express representation to Dr. Swank or herself. To the extent Thompson relies on the statements in the 51(k) submission and the Instruction Leaflet, she has no evidence that the CMW 1 Gentamicin Bone Cement failed to conform to those statements or that she or Dr. Swank relied upon those representations.

Upon review, the Court agrees with DePuy that Thompson has failed to meet her burden on this claim.[13] Thompson identifies three representations made by DePuy: (1) a representation in the 510(k) submission that its bone cement "is a self-curing cement" that "allows for the seating and securing of a metal or plastic prosthesis to living bone"; (2) a representation in the Instruction Leaflet that its bone cement is "used for securing a metal or polymeric prosthesis to living bone in arthroplasty procedures"; and (3) a representation in the Instruction Leaflet that DePuy's bone cement "has no intrinsic adhesive properties, but rely instead on close mechanical interlock between the irregular bone surface and the prosthesis." Assuming the representations concerned the character or quality of the product, there is no evidence that the representations were made to Thompson either directly or through her physician. To the contrary, the evidence presented to the Court shows that Thompson did not know anything about the bone cement or the use of the bone cement before her surgery. There also is no evidence presented that the 510(k) representation made to the FDA also as made *to* Dr. Swank. At best, an inference can be drawn

[13] The Court need not address DePuy's argument that it is not the manufacturer, as issues raised for the first time in a reply brief are deemed waived. *See Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 553 (6th Cir. 2008); *Tonguette v. Sun Life & Health Ins. Co. (U.S.)*, No. 2:12-cv-00006, 2013 U.S. Dist. LEXIS 60716, at *11-12 (S.D. Ohio Apr. 29, 2013). In any event, "suppliers" may be liable under the OPLA for such a claim under certain circumstances. *See* Ohio. Rev. Code § 2307.78(A)(2), (B).

that the existence of the 510(k) representations for the product were something Dr. Swank may consider.

Regardless, Thompson has not shown a genuine issue of material fact as to the bone cement's failure to conform to those representations. With respect to the representation that the bone cement is "a self-curing cement" that "allows for the seating and securing of a metal or plastic prosthesis to living bone," Thompson has presented no evidence that demonstrates her bone cement lacked the qualities necessary to make it self-curing or that such self-curing cement does not allow in any respect for the seating and securing of the prosthesis to the living bone. Instead, she points merely to the fact that the bone cement loosened/was not affixed after three years without any indication as to how that addresses the self-curing nature of the cement or demonstrates that the cement never seated and secured the prosthesis to the living bone. Further, as DePuy points out, the evidence reflects that the tibial plate was properly seated and secured by the bone cement at the conclusion of her surgery and for several years thereafter, and Dr. Mason testified that it was "not necessarily" his conclusion that the bone cement never affixed the implant to the bone. Considering that there is no durational representation made therein, Thompson has not demonstrated a genuine issue of material fact that her bone cement did not conform to that representation.

Likewise, Thompson has presented no evidence that the bone cement is not used for the stated purpose of "securing a metal or polymeric prosthesis to living bone in arthroplasty procedures." Indeed, that is precisely what the bone cement was used for in this instance. Whether the use of bone cement was successful for the intended duration is an entirely separate issue that is not covered by the representation.

Similarly, Thompson has presented no evidence that the bone cement actually has intrinsic adhesive properties or that it does not rely on a close mechanical interlock to work as represented. In fact, Dr. Mason agreed that bone cement does not have inherent adhesive properties and that the function of the bone cement is to prove a mechanical connection between the implant and the bone. Thompson's claim that these representations generally concern the safety and effectiveness of the bone cement is not well taken because such an argument would convert any representation of a manufacturer, regardless of its nature, into representations upon which a non-conformance claim could be based anytime a product failed. Therefore, absent more, the claim for non-conformance with those representations cannot survive.

Even if Thompson had shown a genuine issue of material fact as to non-conformance with the representations, she still has not shown justifiable reliance. Again, the evidence presented to the Court shows that Thompson did not know anything about the bone cement or the use of the bone cement before her surgery. In the absence of such knowledge, she could not have justifiably relied on any such representations. As for Dr. Swank, Thompson has failed to create a genuine issue of material fact that he justifiably relied upon any of those specific representations in deciding to use CMW 1 Gentamicin Bone Cement. Dr. Swank testified that he did not choose the CMW1 Gentamicin Bone Cement based upon any representations. Rather, he used the bone cement because he had used it successfully for years on other patients and had gained a lot of knowledge about bone cement during medical school and his orthopaedic residency. Thompson's speculation that Dr. Swank's testimony "doesn't necessarily establish that he never read the insert at any time or that a DePuy representative never made representations about the cement's quality" (Doc. 41, PageId 1640) does not create a genuine issue of material fact to survive summary judgment. It is Thompson's burden to prove the

requisite elements of her claim, and she had the opportunity to obtain the necessary testimony of Dr. Swank regarding his reliance upon any of the representations in the 510(k) or the Instruction Leaflet. His sole vague statement referencing "a manufacturer's insert or something" (Doc. 33, PageId 865) that does not necessarily rule out that he read the insert at some point provides nothing more than scintilla of evidence in support of her position, which is insufficient. Absent significant evidence on which the jury could reasonably find for Thompson, the element of justifiable reliance is not satisfied.

Accordingly, summary judgment is granted to DePuy on Count Four.

**E. Punitive Damages**

Ohio Rev. Code § 2307.80 governs punitive damages in a product liability case. It provides:

> Subject to divisions (C) and (D) of this section, punitive or exemplary damages shall not be awarded against a manufacturer or supplier in question in connection with a product liability claim unless the claimant establishes, by clear and convincing evidence, that harm for which the claimant is entitled to recover compensatory damages in accordance with section 2307.73 or 2307.78 of the Revised Code was the result of misconduct of the manufacturer or supplier that manifested a flagrant disregard of the safety of persons who might be harmed by that product.

Ohio Rev. Code § 2307.80(A). Of relevance here is division (C)(1)(a) and (C)(2) of this section, under which a manufacturer is not liable for punitive damages for a device that was manufactured and labeled in relevant and material respects in accordance with FDA approval unless the plaintiff can show by a preponderance of the evidence that the "manufacturer fraudulently and in violation of applicable regulations of [the FDA] withheld from the [FDA] information known to be material and relevant to the harm that the claimant suffered or misrepresented to the [FDA] of that type." Ohio Rev. Code § 2307.80(C)(1)-(2).

DePuy moves for dismissal of the request for punitive damages on several grounds. First, it argues that Thompson's bone cement was undisputedly manufactured and labeled in accordance with the governing FDA requirements and Thompson never has claimed that DePuy fraudulently withheld or misrepresented any material or relevant information in obtaining FDA clearance. Second, DePuy argues that the district courts in this circuit have required a finding of fraud or misrepresentation by the FDA, which has not occurred here. Third, DePuy contends that Thompson has no evidence, let alone clear and convincing evidence, demonstrating a flagrant disregard for safety.

Thompson responds that there is no Sixth Circuit case that addresses the issue of whether punitive damages under the Ohio statute are preempted, and she requested documents from DePuy regarding its submission of information to the FDA regarding the change of the Gentamicin from micronized to non-micronized particles which DePuy refused to produce until ordered to do so by the Court. Thompson further insists that punitive damages are an issue to be determined by the trier of fact.

DePuy replies that Thompson has no evidence of conduct warranting punitive damages and Sixth Circuit caselaw precludes any recovery based upon punitive damages.

The Court agrees with DePuy that the reasoning in *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551-52 (6th Cir. 2012) and *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d. 961 (6th Cir. 2004), requires dismissal of the request for punitive damages to the extent it is based on Ohio Rev. Code § 2307.80(C)(2). In *Monroe v. Novartis Pharms. Corp.*, 29 F. Supp. 3d 1115, 1130 (S.D. Ohio 2014), the court analyzed the specific language of Ohio's punitive-damages statute, Ohio Rev. Code § 2307.80 by succinctly tracing how the Sixth Circuit and other courts in this circuit have applied and interpreted *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001), in

which the Supreme Court held that "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." The *Monroe* court explained:

> The Sixth Circuit, looking at Michigan law with a framework similar to Ohio, found that the difference between a common law claim of fraud on the FDA (as discussed in *Buckman*) and immunity under Michigan law unless fraud could be shown was "immaterial in light of *Buckman*." *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004). Instead, the Sixth Circuit held that "**state tort remedies** requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Id.* (emphasis added). The Sixth Circuit has extended this rule, holding that "claims that the manufacturer misrepresented or withheld information about a drug from the FDA after the FDA had approved it" were also preempted. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551 (6th Cir. 2012). One District Court found that "a punitive-damages claim for an FDA-approved drug is allowed under Ohio law *only if* the FDA has made a finding of either fraud or misrepresentation." *In re Gadolinium-Based Contrast Agents Products Liab. Litig.*, MDL No. 1901, 2013 U.S. Dist. LEXIS 20706, 2013 WL 587655, at *14 (N.D. Ohio Feb. 13, 2013).

*Monroe*, 29 F. Supp. 3d at 1130. After considering that history, the court held that the request for punitive damages under Ohio Rev. Code § 2307.80 was barred because there had not been a finding of fraud by the FDA in that case. *Id.* Other courts in this circuit have similarly held that punitive damages were unavailable for an FDA-approved drug under Ohio Rev. Code § 2307.80 where there was no evidence that the FDA had found either fraud or misrepresentation by the manufacturer. *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 U.S. Dist. LEXIS 104564, at *102-03 (S.D. Ohio Aug. 10, 2015); *Williams v. Novartis Pharms. Corp.*, 15 F. Supp. 3d 761, 764-65 (S.D. Ohio 2014); *In re Gadolinium-Based Contrast Agents Products Liab. Litig.*, Nos. 1:08GD50000, 1:12GD50004, 2013 U.S. Dist. LEXIS 20706, at *60-63 (N.D. Ohio Feb. 13, 2013). Given that the Court agrees with the analysis set forth in those cases and there is no evidence presented in this case that the FDA has found either fraud or misrepresentation by DePuy, Thompson's request for punitive damages is dismissed to the extent it is based on Ohio Rev. Code § 2307.80(C)(2).

Moreover, Thompson's claim for punitive damages must be dismissed for lack of clear and convincing evidence as to DePuy's alleged flagrant disregard for the safety of persons who may be harmed by the product. Thompson has set forth no evidence at all as to flagrant disregard, much less any evidence that shows a flagrant disregard by clear and convincing evidence.

Accordingly, Thompson's request for punitive damages shall be dismissed.

## IV. CONCLUSION

Consistent with the foregoing, DePuy's Motion for Summary Judgment (Doc. 29) is **GRANTED IN PART** and **DENIED IN PART**. It is hereby **ORDERED** that the following claims are **DISMISSED**:

1. The claim for strict liability for design defects in Count Two to the extent it is based on the liquid formulation of the CMW 1 Gentamicin Bone Cement;
2. Count Three for strict products liability for defect due to inadequate warning;
3. Count Four for strict products liability for defect due to nonconformance with representations;
4. Count Five for fraudulent and negligent misrepresentations;
5. Any claims to the extent they are based upon violations of federal requirements; and
6. The request for punitive damages.

The case shall proceed on Count One for strict products liability for defective manufacturing and Count Two for defective design based upon the powder component of the CMW 1 Gentamicin Bone Cement.

**IT IS SO ORDERED**.

s/Michael R. Barrett
JUDGE MICHAEL R. BARRETT
UNITED STATES DISTRICT COURT